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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,695	03/27/98	BILLING-MEDEL	P 6066.US.PI

023492
ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
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ABBOTT PARK IL 60064-6050

HM22/1122

EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	18

DATE MAILED: 11/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/049,695	Billing-Medel et al
Examiner	**Group Art Unit**
Karen Can lla	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-3, 7-10, 16, and 19-27* is/are pending in the applicat

Of the above, claim(s) *7-10, 16, and 19-27* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Arguments

1. Please note that the examiner assigned to your application in the PTO has changed.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-3 are under consideration. Claims 7-10, 16 and 19-27 remain withdrawn from consideration.

Claim Rejections Maintained

4. The rejection of claims 1-3 under 35 U.S.C. 101, because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility, is maintained.

Claims 1-3 are drawn to a purified polynucleotide consisting of a polynucleotide selected from the group consisting of SEQ ID NO:1, 2, 23, 24, 25 and complements thereof. The specification describes the isolation of these sequences from cDNA libraries derived from a combination of healthy and diseased gastrointestinal tract tissue. The specification teaches that SEQ ID NO:25 was found in 9 out of 58 GI tissue libraries, including both normal and diseased tissue. The specification does not demonstrate that the detection of these polynucleotide sequences is indicative of the presence of gastrointestinal disease or any other disease. There are no examples or teachings in the specification that would indicate that normal GI tract tissue does not express the polynucleotides of SEQ ID NO:1, 2, 23, 24, 25. The specification does not show any examples linking the diagnosis of a hypertrophic proliferation state such as neoplasia in the GI tract or cancer of the GI tract with the presence of the claimed polynucleotides. There is no teaching correlating the detection of the polynucleotides of SEQ ID NO:1, 2, 23, 24, 25 with metastatic GI tract cancer. Applicant argues that the instant polynucleotides would encode a protein 151 amino acids long which would be useful as a diagnostic marker for GI diseases due to the abundance of CS197 in GI tissued. Applicant point out that since the appearance of CEA and

PSA in blood is indicative of cancer, the appearance of the hypothetical CS197 polypeptide in the blood it would be indicative of cancer of the GI tract. This is not found persuasive. There is no evidence in the specification or any art of record to demonstrate that any of the polynucleotides of SEQ ID NO:1, 2, 23, 24, 25 are actually translated into proteins. Further, if said nucleotides were translated into proteins there is no evidence in the specification or any art of record to demonstrate the shedding of the putative proteins into the bloodstream due to cancer of the GI tract or any other diseases of the GI tract. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids. Because the claimed invention is not supported by a specific, substantial and asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

5. Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. All other rejections and objections recited in Paper No. 14 are withdrawn.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

8. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
November 19, 2000

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600